MAR 2 6 2001

K010013

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
VALLEYLAB LIGASURE™ LAPAROSCOPIC SEALER DIVIDER

I. Submitter Information

Valleylab, a division of Tyco Healthcare
5920 Longbow Drive
Boulder, Colorado 80301
Contact: Kevin M. Randall
Telephone No.: 303-530-6253

Date Summary Prepared: 12/29/2000

II. Name of Device

- Trade or Proprietary Name: LigaSure™ Laparoscopic Sealer Divider
- Common Name: Bipolar Laparoscopic Electrosurgical Instrument
- Classification Name: 21CFR 878.4400 – Electrosurgical Cutting and Coagulation Device and Accessories, and 21 CFR 884.4120 – Gynecologic Electrocautery and Accessories

III. Predicate Devices

The LigaSure™ Laparoscopic Sealer Divider is substantially equivalent to the Circon Cabot Tripolar® 10mm Cutting Forceps (K932293) and the Valleylab LigaSure™ Standard Vessel Sealing Instrument (K981916). All of these devices perform coagulation of tissue via bipolar RF energy applied through the electrodes of the devices. Both the LigaSure™ Laparoscopic Sealer Divider and Circon Cabot Tripolar® 10mm Cutting Forceps divide tissue using a manually actuated blade.

IV. Device Description

The LigaSure™ Laparoscopic Sealer Divider is provided as a sterile, single use device. It is a multifunctional device capable of vessel sealing, blunt dissection, grasping and dividing tissue enclosed within its jaws during laparoscopic procedures. The outer diameter of the instrument shaft is 10 mm, with a working length of 37 cm.

Designed to be used with the Valleylab Vessel Sealing Generator (K981916), the LigaSure™ Laparoscopic Sealer Divider creates vessel ligation by the application of bipolar electrosurgical RF energy (coagulation/desiccation) to vessel tissue or vascular bundles interposed between the electrodes of the device.

V. Intended Use

The LigaSure™ Laparoscopic Sealer Divider is a dedicated bipolar electrosurgical instrument intended for use in general surgical and gynecologic laparoscopic procedures

where division of vessels is desired. The instrument creates a seal by the application of bipolar electrosurgical RF energy (coagulation) to vascular structures (vessels) interposed between the jaws of the device. A blade is actuated for division of tissue.

The indications for use include general laparoscopic procedures including urologic, vascular, thoracic and thoracoscopic, and gynecological laparoscopic procedures where ligation and division of vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomies, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The LigaSure Vessel Sealing System has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this system for these procedures. The LigaSure Laparoscopic Vessel Sealer Divider can be used on vessels up to and including 7 mm and bundles as large as will fit in the jaws of the instrument.

VI. Summary of Technological Characteristics

The LigaSure™ Laparoscopic Sealer Divider has the same basic technological characteristics as the predicate devices noted above.

VII. Performance Data

Preclinical laboratory (acute and chronic studies) and performance testing were performed to ensure the LigaSure™ Laparoscopic Sealer Divider functioned as intended and met design specifications. Sufficient data was obtained to show the device to be substantially equivalent to the predicate devices and meet safety and effectiveness criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2001

Mr. Kevin M. Randall
Regulatory Associate
Valleylab, Inc.
A Division of Tyco Healthcare
5920 Longbow Drive
Boulder, Colorado 80301

Re: K010013
Trade Name: LigaSure™ Laparoscopic Sealer Divider
Regulatory Class: II
Product Code: GEI
Dated: December 29, 2000
Received: January 2, 2001

Dear Mr. Randall:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010013

Device Name: LigaSure™ Laparoscopic Sealer Divider

Indications For Use:

The LigaSure™ Laparoscopic Sealer Divider is a dedicated bipolar electrosurgical instrument intended for use in general surgical and gynecologic laparoscopic procedures where ligation and division of vessels is desired. The instrument creates a seal by the application of bipolar electrosurgical RF energy (coagulation) to vascular structures (vessels) interposed between the jaws of the device. A blade is actuated for division of tissue.

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PLEASE DO NOT WRITE BELOW THIS LINE
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010013

Prescription Use ✓ OR Over-The-Counter Use ____

(Optional Format 1-2-96)